

17.03.2026

Urgent Field Safety Notice

Dear Customers,

DH Healthcare GmbH, a Dedalus Group company, would like to bring to your attention the following issue reported to the national competent authority:

Title: Administration task untraceable due to unexpected deletion of the corresponding prescription line

Internal Reference: MST0085248

Product name and version(s) and UDI-DI:

- ORBIS Medication 03.16.00.00 in ORBIS version 84.38.00.00 and higher in Germany, Austria, Switzerland, Luxembourg
- ORBIS Medication 03.16.01.00 in ORBIS version 84.38.00.00 and 85.21.00.00 and higher for France.
- ORBIS Medication 03.21.02.01 in ORBIS version 84.43.04 and higher in UK

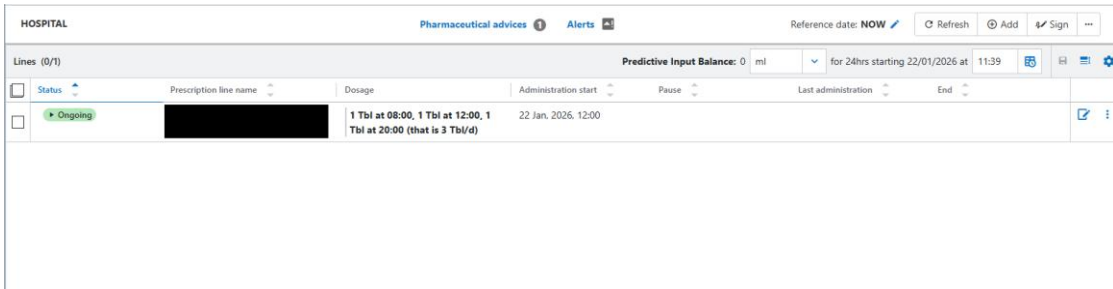
Manufacturer: DH Healthcare GmbH
UDI-DI: 4260693990026

Information:

The following issue occurs in the prescription when, after creating and signing a prescription line, the physician deletes it. In a second time, the physician duplicates it before the first administration. In this case, both prescription lines are deleted, but administration tasks are still generated in the Nursing Intervention Worklist. These tasks then become impossible to administer, as the system indicates that the line has been duplicated, even though no corresponding line exists.

Illustrated scenario:

A physician creates a prescription line and signs.



The screenshot shows a software interface for a hospital. At the top, it says 'HOSPITAL' and 'Pharmaceutical advices Alerts'. There are buttons for 'Reference date: NOW', 'Refresh', 'Add', and 'Sign'. Below this, there is a table with columns: Status, Prescription line name, Dosage, Administration start, Pause, Last administration, and End. The table contains one row with the status 'Ongoing', a redacted prescription line name, and dosage '1 Tbl at 08:00, 1 Tbl at 12:00, 1 Tbl at 20:00 (that is 3 Tbl/d)'. The administration start is '22 Jan, 2026, 12:00'. There are also icons for 'Predictive Input Balance' and 'for 24hrs starting 22/01/2026 at 11:39'.

1 / 5

URGENT FIELD SAFETY NOTICE - MST0085248

DH Healthcare GmbH
Konrad-Zuse-Platz 1-3, 53227 Bonn

Then, before first administration, he deletes and duplicates the line in the same action sequence and signs.

Dossier patient / PID 521268 / 00019 / Liste de prescriptions

HOSPITAL Pharmaceutical advices 1 Alerts ✓ Reference date: NOW [Cancel] [Add] [Sign] [More]


Predictive Input Balance: 0 ml for 24hrs starting 22/01/2026 at 11:56

Status	Prescription line name	Dosage	Administration start	Pause	Last administration	End
<input checked="" type="checkbox"/> To be signed	[REDACTED]	2 Tbl at 08:00, 2 Tbl at 12:00, 2 Tbl at 20:00 (that is 6 Tbl/d)	22 Jan, 2026, 20:00			
<input checked="" type="checkbox"/> To be signed	[REDACTED]	1 Tbl at 08:00, 1 Tbl at 12:00, 1 Tbl at 20:00 (that is 3 Tbl/d)	22 Jan, 2026, 20:00			

Both lines (deleted one and duplicated one) disappear.

HOSPITAL Pharmaceutical advices 1 Alerts ✓ Reference date: NOW [Refresh] [Add] [More]

Predictive Input Balance: 0 ml for 24hrs starting 22/01/2026 at 11:39


 No data found

In parallel, duplication action leads to the creation of new administration tasks in Nursing Intervention WorkList.

Nursing interventions worklist/Nursing interventions WL

Department: [REDACTED] Ward: [REDACTED] STGL: [REDACTED] Room: [REDACTED] Bed: [REDACTED] Time: Interval [Selected] Shift [Unselected]

Start: 22/01/2026 00:01 End: 22/01/2026 19:00

Intervention: [REDACTED] Add'l text: [REDACTED]

Summary: [REDACTED]

Orders: with Without quick confirmation Hide nursing interventions for healthcare assistants

Orders before admission or from pre-admission cases are displayed

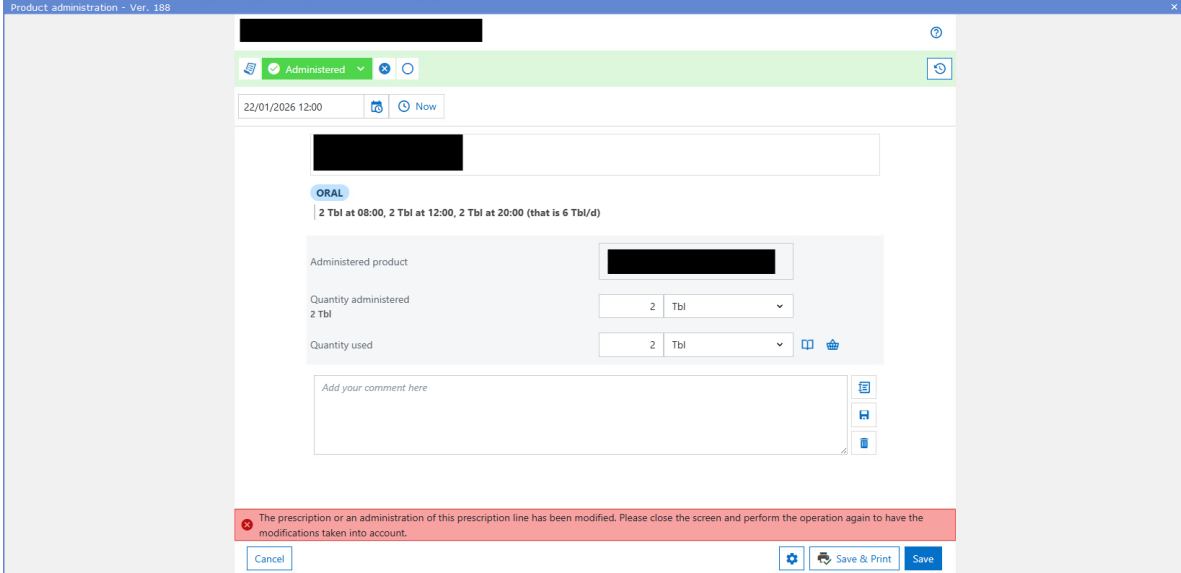
do not display planned cases

Display open orders from discharged cases

ORME 3.15 [ORBIS Medication] Handover WL [Print list] [Open] [Confirm] [Not completed] [Confirm all]

Icon	Time	Room	Bed	Patient	Interventions	Add'l text	Number
	12:00	[REDACTED]	[REDACTED]	[REDACTED]	[PREP] [REDACTED] spec to take by route Oral 2 Tbl at 08:00, 2 Tbl at 12:00, 2 Tbl at 20:00 (that is 6 Tbl/d)		To be prepared
	12:00	[REDACTED]	[REDACTED]	[REDACTED]	First administration expected on January 22 2026 at 12:00 Signed [REDACTED] January 22 2026 at 11:57		
	12:00	[REDACTED]	[REDACTED]	[REDACTED]	[PREP] [REDACTED] spec to take by route Oral 2 Tbl at 08:00, 2 Tbl at 12:00, 2 Tbl at 20:00 (that is 6 Tbl/d)		2 Tbl
	12:00	[REDACTED]	[REDACTED]	[REDACTED]	First administration expected on January 22 2026 at 12:00 Signed [REDACTED] January 22 2026 at 11:57		

If a nurse attempts to administer and confirm these tasks, the system blocks the action, indicating that the prescription has been modified and advising verification. However, the corresponding prescription lines no longer exist.



This behavior can lead to administration errors of prescribed treatment due to nursing tasks being blocked and lacking an associated prescription.

Actions:

Actions undertaken by DH Healthcare GmbH:

- Inform the affected customers with this letter.
- Release of correction with ORBIS Medication version 03.22.00.00 or higher in ORBIS version 84.44.00.00 or higher (release planned for second quarter of 2026 for DACHL and second half of 2026 for UK).
- Release of correction with ORBIS Medication 04.00.00.00 or higher in ORBIS version 84.44.02.00 or higher and 85.44.02.00 or higher (release planned for first quarter of 2027 for FR).

Recommended actions to be taken by the customer:

- As a physician, please execute the deletion and the duplication steps separately:
 - Delete the prescription line and sign.
 - After the first action is completed, duplicate the prescription line as a separate action and sign the new line.
- As a physician, if you face the issue, please always inform the nurses about the specific administration tasks not to be considered from the Nursing Intervention Worklist..
- Install the correction when available.

Please distribute this information to all those who need to be aware of it.

Regardless of the situation described here, we would like to point out that care providers must always ensure that clinically relevant information, including prescription information, is clearly communicated and that they must use verified information (e.g., from medical devices such as monitoring systems), independent from the software being used.

It is important that you take the actions described in this safety information and acknowledge receipt of this letter.

If the above information does not apply to your hospital or if the device has been transferred to another organization, please indicate this on the attached feedback form and forward this Field Safety Notice to the respective organization.

Thank you for your careful attention to this matter and for your support.

If you have any questions on this matter, please consult our contact person:

Sincerely,

Urgent Field Safety Notice

Feedback Form

We kindly ask you to return this feedback form as soon as possible, but at the latest **within 30 days** after receipt of this letter, to the following e-mail address:

Thank you for your cooperation.

Customer / Facility (names of all affected operational facilities):

Address:

Reference

MST0085248 - Administration task untraceable due to unexpected deletion of the corresponding prescription line

Product reference:

ORBIS Medication

Name (contact person)

Position

Phone number

Date

Signature

- I confirm that I have received and understood the safety information.
- The safety information does not apply to my facility.
- The device was transferred to another organization.

Name and address of the other organization: _____

- Please update our contact information as follows:

Customer / Facility:

Address: